



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases among Men and Women in Agriculture (NIEHS)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on November 27, 2015, Pages 74115 – 74116, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or

request more information on the proposed project contact: Dale Sandler, Ph.D., Chief, Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-4668, or e-mail your request, including your address to: sandler@niehs.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture, 0925-0406 (Expiration Date 9/30/2016, REVISION), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to request new components as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA), as well as continue and complete phase IV (2013-2016) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA components are a control respondent group, and a smartphone application (app), along with new sample collection (buccal cell and air monitoring samples). The new components will use similar procedures to ones already employed on the BEEA study, as well as other NCI studies. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural

Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 11,440.

Estimated Annualized Burden Hours

| Type of Respondent | Form Name | Number of Respondents | Number of Responses per Respondent | Average Time Per Response (in hours) | Total Annual Burden Hours |
|--|--|-----------------------|------------------------------------|--------------------------------------|---------------------------|
| Private and Commercial Applicators and Spouses | IA/NC Scripts for Verbal Consent for Buccal | 100 | 1 | 3/60 | 5 |
| Private and Commercial Applicators and Spouses | IA/NC Written Consent for Buccal | 100 | 1 | 5/60 | 8 |
| Private and Commercial Applicators and Spouses | Buccal Follow-up Scripts (as needed): Reminder, Missing Consent, or Damaged/Missing Sample | 30 | 1 | 2/60 | 1 |
| Private Applicators | BEEA CATI Screening Script for RSG, REG or AMG Eligibility | 480 | 1 | 20/60 | 160 |
| Private Applicators | IA/NC BEEA Consent for RSG Home Visit or REG Home Visit or AMG Home Visit | 196 | 1 | 5/60 | 16 |
| Private Applicators | IA/NC BEEA RSG Pre-Visit Show Card | 160 | 1 | 5/60 | 13 |
| Private Applicators | IA/NC BEEA RSG Paper/Pen Dust Questionnaire | 160 | 1 | 10/60 | 27 |
| Private Applicators | BEEA RSG Pre-Home Visit Script | 160 | 1 | 2/60 | 5 |
| Private Applicators | BEEA RSG Home Visit CAPI, Blood, Buccal cell, Urine & Dust | 160 | 1 | 90/60 | 240 |
| Private Applicators | IA/NC BEEA REG Pre-Visit Show Card | 20 | 3 | 5/60 | 5 |
| Private Applicators | IA/NC BEEA REG Paper/Pen Dust Questionnaire | 20 | 3 | 10/60 | 10 |

| | | | | | |
|---------------------|---|-----|----|-------|-----|
| Private Applicators | BEEA REG Pre-Home Visit Script | 20 | 3 | 2/60 | 2 |
| Private Applicators | BEEA REG Home Visit CAPI, Blood, Buccal cell, Urine & Dust | 20 | 3 | 90/60 | 90 |
| Private Applicators | IA/NC BEEA REG Post-Exposure Scheduling Script | 20 | 1 | 2/60 | 1 |
| Private Applicators | IA/NC BEEA AMG Pre-Visit Show Card | 16 | 2 | 5/60 | 3 |
| Private Applicators | IA/NC BEEA AMG Paper/Pen Dust Questionnaire | 16 | 2 | 10/60 | 5 |
| Private Applicators | BEEA AMG Pre-Home Visit Script | 16 | 2 | 2/60 | 1 |
| Private Applicators | BEEA AMG Home Visit CAPI, Blood, Urine, Buccal cell & Dust | 16 | 2 | 90/60 | 48 |
| Private Applicators | IA/NC BEEA Consent for AMG Farm Visit | 16 | 1 | 5/60 | 3 |
| Private Applicators | BEEA Pre-Farm Visit Script | 16 | 2 | 2/60 | 1 |
| Controls | BEEA CATI Control Eligibility Script | 215 | 1 | 20/60 | 72 |
| Controls | IA/NC BEEA Control Home Visit Consent | 67 | 1 | 5/60 | 6 |
| Controls | IA/NC BEEA Pre-Visit Show Card | 67 | 1 | 5/60 | 6 |
| Controls | IA/NC BEEA Paper/Pen Dust Questionnaire | 67 | 1 | 10/60 | 11 |
| Controls | BEEA REG Pre-Visit Script | 67 | 1 | 2/60 | 2 |
| Controls | BEEA Control Home Visit CAPI, Blood, Buccal cell, Urine, & Dust | 67 | 1 | 90/60 | 101 |
| Private Applicators | 'Life in a Day' Smartphone App Consent and Setup | 78 | 1 | 20/60 | 26 |
| Private Applicators | 'Life in a Day' Smartphone Application | 78 | 30 | 10/60 | 390 |

| | | | | | |
|---------------------|--|--------|--------|-------|--------|
| Private Applicators | Phase IV Follow-up CAWI, CATI, or Paper/pen | 13,855 | 1 | 25/60 | 5,773 |
| Spouses | Phase IV Follow-up CAWI, CATI, or Paper/pen | 10,201 | 1 | 25/60 | 4,250 |
| Proxy | Phase IV Follow-up CAWI, CATI, or Paper/pen | 635 | 1 | 15/60 | 159 |
| Total | | 27,139 | 29,641 | | 11,440 |

Dated: April 4, 2016

Jane M. Lambert, CIP

Project Clearance Liaison

NIEHS

[FR Doc. 2016-08397 Filed: 4/11/2016 8:45 am; Publication Date: 4/12/2016]